3M™ Attest™ Auto-reader 490

- (GB) Operator's Manual
- (FR) Manuel de l'utilisateur
- (DE) Benutzerhandbuch
- (IT) Manuale dell'operatore
- (ES) Manual del usuario
- (ES) Manual del operador
- (NL) Bedieningshandleiding
- (SE) Användarhandbok
- (DK) Brugsvejledning
- (NO) Brukerhåndbok
- (FI) Käyttöopas
- (PT) Manual do Utilizador
- (PT) Manual do Operador
- (GR) Εγχειρίδιο Χειριστή
- (PL) Instrukcja obsługi
- (CZ) Příručka pro obsluhu
- (SI) Priročnik za uporabo
- (RU) Инструкция по эксплуатации
- (HR) Upute za korištenje
- (TR) Operatör Kılavuzu
- (CN) 操作指南
- (TH) คู่มือปฏิบัติงาน
- (KR) 작업자 매뉴얼

3M™ Attest™ Auto-reader 490

Read and understand all safety information before using this product.

TABLE OF CONTENTS

Preface 2
Intended Use 2
Warranty 2
Safety and Precautions 2
Health and Safety Information 3
Explanation of Product and Packaging Label Symbols 3
Specifications 4
Instructions for Use 4
Features 7
Care and Cleaning 8
Troubleshooting Guide 8
Optional 3M™ Attest™ Auto-reader 490 Web App 9
Troubleshooting the 3M™ Attest™ Auto-reader 490 Web App 12
Repair and Replacement 12

GB

PREFACE

Manual Revision History

Date	Revision	Reason For Revision
SEP 2010	A	Initial Issue
FEB 2012	B	To include the incubation of 3M™ Attest™ Super Rapid Readout Biological Indicators 1492V in the 3M™ Attest™ Auto-reader 490 and add statements clarifying access to the 3M™ Attest™ Auto-reader 490 Web App within a secure network.
JUN 2013	C	To revise: the Warranty statement; and the WEEE and C-Tick symbols and associated explanatory text.

Content Disclaimers

Pictorial Disclaimer

Sample printouts, graphics, displays and screens are for information and illustration purposes only, and shall not be used for clinical or maintenance evaluations. Data shown in sample printouts and screens do not reflect actual patient names or test results.

Hardware Disclaimer

The 3M™ Attest™ Auto-reader 490 hardware specifications are subject to change. The system images, hardware components and hardware specifications included in the manual may not match the system installed. Any changes or modifications to the authorized system installation have been verified as compatible with the functionality outlined in this document.

INTENDED USE

The 3M™ Attest™ Super Rapid Readout Biological Indicator System provides rapid, reliable monitoring of steam sterilization processes performed in health care facilities. The system is comprised of biological indicators, challenge packs, and an incubator/reader (3M™ Attest™ Auto-reader 490) with embedded software.

The 3M™ Attest™ Auto-reader 490 is designed to incubate and automatically read 3M™ Attest™ Super Rapid Readout Biological Indicators 1491 at 56°C for a final negative fluorescence reading at 30 minutes and 3M™ Attest™ Super Rapid Readout Biological Indicators 1492V at 56°C for a final negative fluorescence reading at 1 hour.

The 3M™ Attest™ Auto-reader 490 is also designed to allow for further incubation of 3M™ Attest™ Super Rapid Readout Biological Indicators, catalog numbers 1491 and 1492V, for a final negative, visual pH color change result at 24 hours and 48 hours, respectively. This further incubation is optional and not intended for routine use.

A positive fluorescence reading or a visual pH color change indicate a steam sterilization process failure. However, due to the high sensitivity of the fluorescent result, there is no advantage to continuing to incubate processed 3M™ Attest™ Super Rapid Readout Biological Indicators once the fluorescent result has been documented.

Other biological indicators (BIs) are not compatible with this device and cannot be used.

The unit is designed to be used only with the Power Supply module and Ethernet cable supplied by 3M.

WARRANTY

The 3M™ Attest™ Auto-reader 490 has a one year limited product warranty. The US warranty, remedy and limitations are described in the Price Quote form and in the Direct Price Pages. For countries outside of the US, any warranty is established by the subsidiary with responsibility for service of the 3M™ Attest™ Auto-reader 490.

Serial Number

For easy identification, each 3M™ Attest™ Auto-reader 490 has a unique serial number printed on a label (SN / DATE CODE) found on the back of the unit and displayed on the left side of the upper row of text on the LCD Display when the user depresses the button. Please record your serial number in this manual for future reference: _____.

SAFETY AND PRECAUTIONS

The 3M™ Attest™ Auto-reader 490 and its related devices and accessories are designed to provide safe and reliable service when used according to the instructions provided. Please read, understand, and follow all safety information contained in the instructions for use included with the 3M™ Attest™ Auto-reader 490 and Super Rapid Readout Biological Indicator devices prior to use. Use this equipment only for the purpose described in the Operator's Manual. **Retain these instructions for future reference.**

If this product is used in a manner not specified, the protection provided by the product may be impaired.

Explanation of Single Word Consequences

WARNING: Indicates a hazardous situation, which, if not avoided, could result in death or serious injury.

CAUTION: Indicates a hazardous situation, which, if not avoided, could result in minor or moderate injury.

Warnings and Safety Precautions

The following warnings and precautions should be followed to avoid unsafe actions that could result in personal injury or damage to the instrument.

WARNING: To reduce the risk associated with hazardous voltage
Use indoors only.
Do not use the equipment if it is not working properly or if it has suffered any damage.
Use only the power supply specified for this product and certified for the country of use.

CAUTION: To reduce the risk of injury or instrument damage
Do not spill liquid onto or into the instrument. Do not immerse the unit in liquid.
Always unplug the 3M™ Attest™ Auto-reader 490 and allow to cool before cleaning.
Clean external surfaces using only the instructions provided by the manufacturer.
Do not open the instrument housing – there are no user serviceable parts.
The instrument must be returned to the manufacturer for repair.
Allow the 3M™ Attest™ Super Rapid Readout Biological Indicator to cool for the recommended time period before activating. Activating or excessive handling of the biological indicator before cooling may cause the glass ampoule to burst.
Wear safety glasses when activating the 3M™ Attest™ Super Rapid Readout Biological Indicator.

⚠ **WARNING:** To reduce the risk associated with incorrect results
Instrument is to be used by operators familiar with the device, device functionality, and Operator's Manual.
Do not place the instrument in environment exposed to sunlight or strong incandescent light.
Do not place instrument close to any device that emits a strong electro-magnetic field.
Do not use on a vibrating surface.
Match the cap color of the 3M™ Attest™ Super Rapid Readout Biological Indicator with the color-coded configuration sticker surrounding the 3M™ Attest™ Auto-reader 490 incubation wells.
Do not remove or change placement of 3M™ Attest™ Super Rapid Readout Biological Indicator once it is placed into a well.
Do not remove the 3M™ Attest™ Super Rapid Readout Biological Indicator from the incubation well until the (+) or (-) symbol on the LCD panel indicates the test is complete.

⚠ **CAUTION:** To reduce the risk associated with incorrect results
To avoid the possibility of the 3M™ Attest™ Super Rapid Readout Biological Indicator vial absorbing fluorescent residue from a chemical indicator or tape, place the 3M™ Attest™ Super Rapid Readout Biological Indicator vial so it does not come in direct contact with chemical indicators or tape.

HEALTH AND SAFETY INFORMATION

Device Safety Compliance

The 3M™ Attest™ Auto-reader 490 complies with the following standards as demonstrated by the CB Scheme Certificate and test report issued by Underwriters Laboratories (UL):

- IEC 61010-1 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
- IEC 61010-2-010 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of materials
- IEC 60825-1 First Edition Safety of laser products - Part 1: Equipment classification, requirements, and user's guide

The 3M™ Attest™ Auto-reader 490 is listed as Laboratory equipment and carries the UL mark with adjacent indicators "C" and "US" based on compliance to the standards UL 61010-1 and CAN/CSA 22.2 No. 61010-1.

The 3M™ Attest™ Auto-reader 490 complies with the CE mark related to the Low Voltage Directive 73/23/EEC as confirmed in the Declaration of Conformity.

The 3M™ Attest™ Auto-reader 490 complies with the RoHS Directive, Directive 2002/95/EC of the European Parliament and of the Council on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

EMC Compliance

The 3M™ Attest™ Auto-reader 490 complies with the following EMC standards as confirmed in the Certificate of Compliance generated by 3M:

IEC 61326-1 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements

The 3M™ Attest™ Auto-reader 490 complies with the EMC requirements of the CE mark EMC Directive 2004/108/EC.

The 3M™ Attest™ Auto-reader 490 complies with the Australian and New Zealand electrical safety and electromagnetic compatibility requirements as confirmed in the Supplier's Declaration of Conformity that is linked to the Australian/New Zealand RCM (Regulatory Compliance Mark).

Note: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide a reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at their own expense.

This Class A digital apparatus meets all requirements of the Canadian Interference-Causing Equipment Regulations.

Class 1 LED Product

An investigation was conducted on the 3M™ Attest™ Auto-reader 490 per the requirements of IEC 60825-1 Ed. 1.2 (A2:2001). The 3M™ Attest™ Auto-reader 490 is a Class 1 LED product with Class 1 Internal Radiation. The magnitude of the maximum radiant power is 5.25uW.

The LED apertures are located at the bottom of each Incubator/Reader well perpendicular to the opening of each well.

Note: Class 1 products are safe for unprotected exposure of the eyes.

Caution - Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.

Note: The use of the term "controls" in the above caution statement as required by IEC 60825-1 Ed. 1.2 (A2:2001) refers to mechanisms by which the 3M™ Attest™ Auto-reader 490 may be controlled and not to the use of biological indicator controls.

EXPLANATION OF PRODUCT AND PACKAGING LABEL SYMBOLS

Attention - Refer to the instructions for use

Waste Electrical and Electronic Equipment (WEEE) and EU Battery Directive. This symbol indicates that both the device and the lithium ion battery contained therein need to be disposed of properly.

UL Listed to US and Canadian Safety Standards

Mark of Conformity to European Directives

Direct current

Compliant to all applicable ACMA regulatory arrangements (RCM)

Manufacturer – This symbol is accompanied by name and address of the manufacturer.

Catalog – This symbol is accompanied by the catalog number relevant to the device bearing the symbol.

Authorized representative for the European Community – This symbol is accompanied by the name and the address of the authorized representative in the European Community.

GB

SPECIFICATIONS

Power Supply Specifications

Power supply	Operating Condition	Units
Voltage Range	100-240	Volts AC
Frequency	50/60	Hertz
Current	0.6	Amps

Environmental Operating Conditions

Environmental Condition	Operating Condition	Units
Altitude	3000 (max)	Meters
Operating Temperature	16 – 40	ºC
Storage Temperature	-10 to 50	ºC
Operating Relative Humidity	20-80 (non-condensing)	%
Voltage Range	12	Volts DC
Frequency	DC	
Current	1.2	Amps
Installation/Over Voltage	Category II	
Pollution Degree	2	

INSTRUCTIONS FOR USE – Initial Set-up

Choose Location

Place 3M™ Attest™ Auto-reader 490 on a firm level surface away from sunlight and incandescent light. To save counter space, units may be stacked two high.

WARNING:

- Do not place the instrument in environment exposed to sunlight or strong incandescent light.
- Do not place instrument close to any device that emits a strong electro-magnetic field.
- Do not use on a vibrating surface.

Select & Install Correct Power Plug

The 3M™ Attest™ Auto-reader 490 power supply comes with multiple blade configurations. Install the blade configuration appropriate for your country into the power supply and plug into appropriate AC grounded outlet.

WARNING: Use only the power supply specified for this product and certified for the country of use.

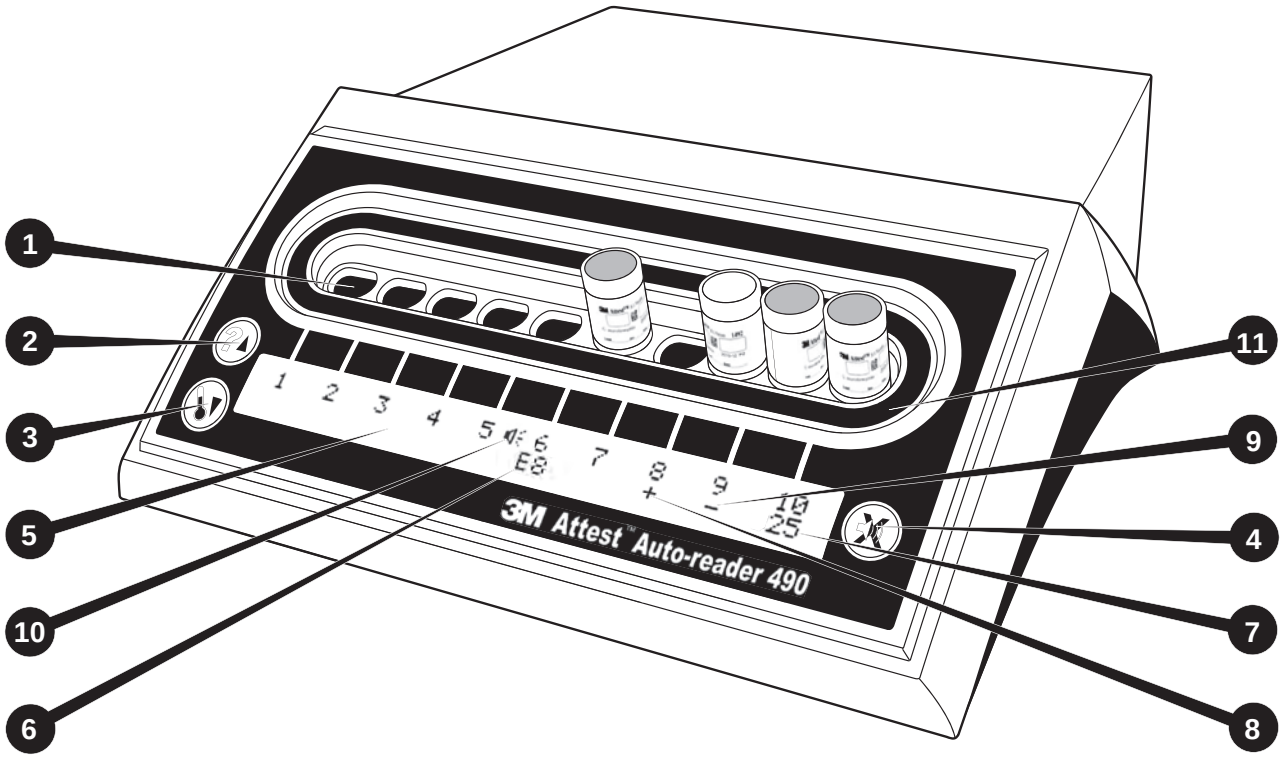
Wait 30 Minutes Before Using

Once plugged in, allow a 30 minute warm-up period before placing 3M™ Attest™ Super Rapid Readout Biological Indicators into the incubation wells. The C1 caution code will disappear when proper incubation temperature is reached.

Special Considerations

It is recommended that the unit be left on to eliminate warm-up periods. The unit may be turned off when it is anticipated that it will not be used for an extended period.

INSTRUCTIONS FOR USE – Wells, Buttons, & Display Interpretation



Please familiarize yourself with the face of the 3M™ Attest™ Auto-reader 490:

Wells

1. Incubation/Reader Wells – The 3M™ Attest™ Auto-reader 490 has ten incubation wells.

Buttons

2. Information / Up Arrow Button
3. Temperature / Down Arrow Button
4. Buzzer Alarm OFF / Enter Button

Information Display

5. LCD Display – Display is backlit.
6. LCD Display – Example of Error Message for well #6
7. LCD Display – Example of Remaining Incubation Time for well #10
8. LCD Display – Example of Positive (+) BI result for well #8
9. LCD Display – Example of Negative (-) BI result for well #9
10. LCD Display – Alarm Enabled Indicator

Color-Coded Configuration Indicator

11. Color-coded incubation well configuration sticker

INSTRUCTIONS FOR USE – 3M™ Attest™ Auto-reader 490 Configuration

Note: Ideally, the 3M™ Attest™ Auto-reader 490 should be empty (i.e. have no incubating BIs) when it is reconfigured.

Press the and buttons on the front of the 3M™ Attest™ Auto-reader 490 simultaneously for 3 seconds to enter configuration mode. Once in configuration mode, use the Up and Down buttons to set the 3M™ Attest™ Auto-reader 490 clock, buzzer and incubation well configuration as desired. The button acts as an "Enter" key and moves the flashing cursor to the next changeable setting.

Setting the 3M™ Attest™ Auto-reader 490 Clock

The 3M™ Attest™ Auto-reader 490 date and time are displayed in this format: YYYY-MM-DD HH:MM, with the time displayed using a 24 hour clock. To change the year, if necessary, push the up or down buttons to set desired year, then press to advance to the month, adjust as necessary and press to advance to the day. Use the button to move to the time and set the hours and minutes.

Setting the Audible Alarm Function

Move across the top row of text by pushing the button. The flashing "B" in Buzzer indicates this is a changeable setting. It is recommended this be set at "Buzzer Enabled" to audibly alert the operator to a positive BI but it may be set to "Buzzer Disabled" by using either the up or down button.

Note: If Buzzer Disabled is selected, and the changes accepted, the speaker icon ( ) will disappear from the LCD panel and the alarm will be disabled for all positive 3M™ Attest™ Super Rapid Readout Biological Indicators, error codes, and caution code alarm warnings.

Note: The 3M™ Attest™ Auto-reader 490 Display backlight flashes whenever an audible alarm sounds. Disabling the audible alarm does NOT disable the LCD display backlight flashing.

Press to select the desired option and advance to the bottom row of text.

GB

Setting the Incubation Well Configuration

Incubation wells 1-5 and 6-10 can be configured to run the same or different types of 3M™ Attest™ Super Rapid Readout Biological Indicators. The flashing "A" in Attest indicates the setting may be changed by the user. There are three incubation well configuration options:

LCD Panel Configuration Setting	Result
Attest 1491 Attest 1492	Auto-reader wells 1 - 5 configured for 1491 BIs (blue cap, 30 minute readout) and wells 6 - 10 configured for 1492V BIs (brown cap, 1 hour readout)
Attest 1491 Attest 1491	Auto-reader wells 1 – 10 configured for 1491 BIs (blue cap, 30 minute readout)
Attest 1492 Attest 1492	Auto-reader wells 1 – 10 configured for 1492V BIs (brown cap, 1 hour readout)

Use the Up Arrow or Down Arrow buttons to move between the three options until the desired configuration setting is displayed.

Press ⓧ to select the desired option and advance to the Accept screen.

Note 1: If there are any incubating BIs which do not yet have a final result (+ or -) displayed, the well configuration for the occupied wells will NOT change until the final result is displayed on the LCD panel and the BI is removed from the reader.

Note 2: Ensure the color-coded incubation well configuration sticker surrounding the incubation wells matches the programmed well configuration.

Accept Screen

Use the up or down buttons to toggle between Yes and No, press ⓧ to accept changes (Yes selected) or retain current settings (No selected) and exit the configuration mode. The LCD panel will return to the standard display.

INSTRUCTIONS FOR USE - Readout Procedure

Instructions for Biological Indicator (BI) Activation and Incubation

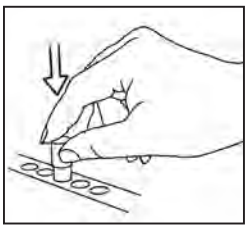
⚠ **CAUTION:** Allow the 3M™ Attest™ Super Rapid Readout Biological Indicator to cool for the recommended time period before activating. Activating or excessive handling of the biological indicator before cooling may cause the glass ampoule to burst.

⚠ **CAUTION:** To avoid the possibility of the 3M™ Attest™ Super Rapid Readout Biological Indicator vial absorbing fluorescent residue from a chemical indicator or tape, place the 3M™ Attest™ Super Rapid Readout Biological Indicator vial so it does not come in direct contact with chemical indicators or tape.

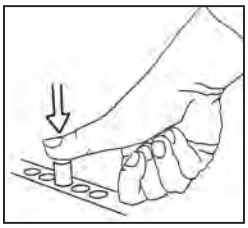
⚠ **WARNING:** Match the cap color of the 3M™ Attest™ Super Rapid Readout Biological Indicator with the color-coded configuration sticker surrounding the 3M™ Attest™ Auto-reader 490 incubation wells.

⚠ **CAUTION:** Wear safety glasses when activating the 3M™ Attest™ Super Rapid Readout Biological Indicator.

Follow this procedure for every 3M™ Attest™ Super Rapid Readout Biological Indicator to be read:



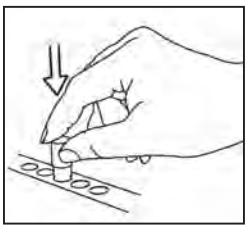
While wearing safety glasses, **PLACE** 3M™ Attest™ Super Rapid Readout Biological Indicator (BI) in **color-coded** 3M™ Attest™ Auto-reader 490 well. Note that BI vial is keyed for specific orientation in well (flat back of BI faces back of 3M™ Attest™ Auto-reader 490).



CLOSE BI cap and **CRUSH** media ampoule by firmly pushing vial straight down in incubation well.

Immediately remove BI, visually **VERIFY** the glass ampoule (containing growth media) has been crushed, and **FLICK** BI to ensure purple growth media flows to the growth chamber at the bottom of the vial.

Note: If the audible alarm is enabled it will sound when the BI is removed from the incubation well if the reader has begun incubation countdown.



RETURN the crushed BI to the 3M™ Attest™ Auto-reader 490 well and observe 3M™ Attest™ Auto-reader 490 LCD panel to confirm correct placement of the BI. If the BI is correctly seated, the 3M™ Attest™ Auto-reader 490 LCD panel will display ***, **, * and then remaining minutes of incubation directly below the incubating BI.

RECORD BI result.

⚠ **WARNING:** Do not remove the 3M™ Attest™ Super Rapid Readout Biological Indicator from the incubation well until the (+) or (-) symbol on the LCD panel indicates the test is complete.

INSTRUCTIONS FOR USE – Additional Information

BI Placement

Wells are configured and color coded to match the cap of the 3M™ Attest™ Super Rapid Readout Biological Indicator i.e., the 3M™ Attest™ Super Rapid Readout Biological Indicator 1491 with a blue cap goes into a blue well and the 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V with a brown cap goes into a brown well.

Remaining incubation time, in minutes, will be displayed on the LCD display to indicate the 3M™ Attest™ Super Rapid Readout Biological Indicator is incubating in the reader well and should **not** be touched. The time remaining display indicates the results are not available and incubation is in progress.

Do not remove 3M™ Attest™ Super Rapid Readout Biological Indicators until the (+) or (-) symbol on the LCD panel indicates the test is complete.

Note: If 3M™ Attest™ Super Rapid Readout Biological Indicators are inadvertently removed before the incubation period is complete, an alarm will sound and a C2 Caution code will also be displayed on the LCD panel under that well. You **must return the 3M™ Attest™ Super Rapid Readout Biological Indicator to the reader well within 10 seconds or the results will be lost.**

⚠ **WARNING:** Do not remove or change placement of 3M™ Attest™ Super Rapid Readout Biological Indicator once it is placed into a well. Doing so may result in loss of results and the 3M™ Attest™ Super Rapid Readout Biological Indicator test may be invalid.

INSTRUCTIONS FOR USE – Positive Control

Positive Control

Activate and incubate at least one non-processed 3M™ Attest™ Super Rapid Readout Biological Indicator to use as the positive control each day that a processed 3M™ Attest™ Super Rapid Readout Biological Indicator is incubated and read by the unit. Write a "C" (for "control") and the date on the label. The positive control can be placed in any appropriately configured (i.e., blue or brown) incubator well. The positive control should be the same Part number, and have the same lot number as the processed 3M™ Attest™ Super Rapid Readout Biological Indicator in the unit.

It is good practice to use a positive control each day a processed 3M™ Attest™ Super Rapid Readout Biological Indicator is incubated. This helps confirm:

- correct incubation temperatures are met (heater block reading of 56.5 ºC +/-2ºC).
- viability of spores has not been altered due to improper storage temperature, humidity, or proximity to chemicals
- capability of media to promote rapid growth, and
- proper functioning of 3M™ Attest™ Auto-reader 490 components.

INSTRUCTIONS FOR USE – Interpretation of Results

Fluorescent Results

After placing a 3M™ Attest™ Super Rapid Readout Biological Indicator into a corresponding color-coded well, the 3M™ Attest™ Auto-reader 490 LCD panel will display ***, **, * and then the remaining minutes of incubation directly below the incubating BI to indicate that incubation/reading is in progress.

A (+) will display on the LCD panel directly under the BI and an alarm will sound (if the sound feature is enabled), as soon as a positive 3M™ Attest™ Super Rapid Readout Biological Indicator result is detected.

At the end of the specified incubation time, if a negative 3M™ Attest™ Super Rapid Readout Biological Indicator result is detected, a (-) will display on the LCD panel directly under the incubating BI. The final negative fluorescent result (-) for a processed 3M™ Attest™ Super Rapid Readout Biological Indicator after 30 minutes or 1 hour of incubation, for 1491 and 1492V BIs, respectively, indicates an acceptable sterilization process. The positive control should read positive (+).

After either the + or – symbol is displayed, and the result is recorded, the 3M™ Attest™ Super Rapid Readout Biological Indicator can be removed from the well. The 3M™ Attest™ Super Rapid Readout Biological Indicator should not be removed or touched when the display indicates remaining incubation time.

The positive (unprocessed) control 3M™ Attest™ Super Rapid Readout Biological Indicator must provide a positive fluorescent result (+). Processed 3M™ Attest™ Super Rapid Readout Biological Indicator results are not valid until the positive control reads fluorescent positive (+). With a processed 3M™ Attest™ Super Rapid Readout Biological Indicator, a positive (+) result indicates a steam sterilization process failure.

Act on any positive test results immediately. Determine the cause of the positive 3M™ Attest™ Super Rapid Readout Biological Indicator following current facility policies and procedures. Always retest the sterilizer and do not use the sterilizer for processing loads until 3 consecutive 3M™ Attest™ Super Rapid Readout Biological Indicator results are negative.

Optional Visual pH Color Change Result

3M™ Attest™ Super Rapid Readout Biological Indicators may be further incubated for a visual pH color change. This optional further incubation is not intended for routine use and may be used for special studies. Due to the high sensitivity of the fluorescent result, there is no advantage to incubating the 3M™ Attest™ Super Rapid Readout Biological Indicators 1491 and 1492V beyond 30 minutes and 1 hour, respectively. After activation and during incubation, the white Nonwoven Material in the biological indicator will absorb bromocresol purple indicator, the pH-sensitive indicator dye in the growth media, and appear blue. In the case of a positive control BI, a yellow color change of the growth media and/or Nonwoven Material will appear within 24 hours for 1491BIs and within 48 hours for 1492V BIs. Any observation of a yellow color within the vial indicates a positive result. In the case of a processed BI, a media and/or Nonwoven material color change from purple to yellow indicates a steam sterilization process failure. A negative pH color change result, i.e. media and Nonwoven Material remain purple/blue, can be assessed at 24 hours for 1491 BIs and at 48 hours for 1492V BIs.

INSTRUCTIONS FOR USE – Disposal

Instrument contains a lithium battery. Dispose of instrument in accordance with federal, state, and local requirements.

FEATURES OF THE 3M™ ATTEST™ AUTO-READER 490

Audible Alarm

An audible alarm will sound, the LCD Display backlight will flash, and a (+) symbol be displayed on the LCD panel directly under the incubating BI when a positive result is detected. An alarm will also sound if a 3M™ Attest™ Super Rapid Readout Biological Indicator is removed from the 3M™ Attest™ Auto-reader 490 well before a final result has been detected. Data will be lost if the 3M™ Attest™ Super Rapid Readout Biological Indicator is not replaced in the incubation well within 10 seconds.

Alarm On/Off

The audible alarm for positive results can be turned off for a particular 3M™ Attest™ Super Rapid Readout Biological Indicator. This is accomplished by pressing the "Buzzer Alarm OFF" button after the alarm has sounded. This will turn off the alarm for that Super Rapid Readout Biological Indicator only. Any positive 3M™ Attest™ Super Rapid Readout Biological Indicator results subsequently detected in other wells will result in the alarm sounding. Removing the 3M™ Attest™ Super Rapid Readout Biological Indicator will reactivate the alarm for that well. Pressing the "Buzzer Alarm OFF" button will not silence the alarm for error or caution code alarm warnings. To disable the alarm, see configuration section.

Stackable

To save counter space, 3M™ Attest™ Auto-reader 490s may be stacked two high.

Information Button

When the Information button is pressed once the 3M™ Attest™ Auto-reader 490 displays two lines of text in the LCD display.

The top row indicates (left to right):

- 3M™ Attest™ Auto-reader 490 serial number
- 3M™ Attest™ Auto-reader 490 embedded software version (V X.Y.Z)
- Current date and time.

The bottom row indicates (left to right):

- The BI type configuration for wells 1-5.
- The BI type configuration for wells 6-10.

Press the information button twice and the 3M™ Attest™ Auto-reader 490 LCD panel will display:

- Top row: Dynamic IP address (if unit is connected to an Ethernet jack)
- Bottom row: Date (YYYY-MM-DD) and time that power was supplied to the 3M™ Attest™ Auto-reader 490.

Temperature Monitoring

The 3M™ Attest™ Auto-reader 490 contains an internal temperature self-diagnostic program. Should the temperature fall outside the specified range (56.5ºC +/-2ºC) an error code will be displayed. The heater block temperature may be checked by depressing the Temperature Button once.

Easy Configuration

The 3M™ Attest™ Auto-reader 490 may be configured using either the buttons located on the front of the unit or using the optional 3M™ Attest™ Auto-reader 490 Web App.

Optional 3M™ Attest™ Auto-reader 490 Web App

If desired, the 3M™ Attest™ Auto-reader 490 may be connected to a PC via an Ethernet connection for additional capabilities:

- Remotely view current status of BIs in the 3M™ Attest™ Auto-reader 490 via PC or mobile hand held devices. For full functionality, the use of an HTML5 compliant browser with JavaScript enabled is recommended.
- Remotely view and configure 3M™ Attest™ Auto-reader 490 settings
- View the last 100 BI records
- Print out documentation using a local or networked printer and/or save documentation as an electronic file.*

Note: To access the 3M™ Attest™ Auto-reader 490 Web App within a secure network, the PC or mobile device must have access to the secure network; options include connecting via a network Ethernet cable, signing in to the facility's wireless network, or connecting via a virtual private network (VPN).

* Refer to your facility's record keeping policy and procedure.

GB

CARE AND CLEANING

⚠ **CAUTION:** Always unplug the 3M™ Attest™ Auto-reader 490 and allow to cool before cleaning.
Do not spill liquid onto or into the instrument. Do not immerse the unit in liquid.
Clean external surfaces using only the instructions provided by the manufacturer.
The instrument must be returned to the manufacturer for repair.

Clean the exterior surface of the 3M™ Attest™ Auto-reader 490 by wiping it with a damp cloth moistened with a mild detergent. Do not attempt to clean interior components. If additional cleaning of the wells is required, call for repair or replacement.

Note: The 3M™ Attest™ Auto-reader 490 does not contain any user serviceable parts or require any routine maintenance. Any malfunctions will be indicated by an error code. Refer to the Troubleshooting Guide section for error code explanations.

TROUBLESHOOTING GUIDE

In the event of an error code, unplug the 3M™ Attest™ Auto-reader 490 and plug it back in to initiate the self-diagnostic test. If error code re-occurs, call for repair or replacement.

The LCD Display panel will indicate detected malfunctions by displaying a caution or error code under affected BI wells. The audible alarm, if active, sounds and the LCD Display backlight flashes to alert the user to all caution (except C1) and error codes. The alarm and backlight can be silenced and extinguished, respectively, by pressing the Buzzer Alarm OFF button . Note that disabling the audible alarm does not disable the flashing LCD Display backlight. Refer to the following:

Code	Problem	Solution
C1	Unit Warm-up Caution Incubation block not at temperature.	Allow a 30 minute warm-up after 3M™ Attest™ Auto-reader 490 is plugged in. (Note: 3M™ Attest™ Super Rapid Readout BI readings are disabled until incubator block reaches 56.5ºC +/-2ºC).
C2	BI Removed from Well Caution 3M™ Attest™ Super Rapid Readout BI has been removed before incubation is complete.	Replace 3M™ Attest™ Super Rapid Readout BI in proper well within 10 seconds to prevent loss of collected data.
C4	Ambient Light Caution	Move 3M™ Attest™ Auto-reader 490 to reduced ambient light conditions.
E1	Temperature Control Error This error will occur if system is no longer able to control the temperature of the incubator block (56.5ºC +/-2ºC).	Cycle power to clear error. If error doesn't clear, call for repair or replacement.
E3	Memory Error 3M™ Attest™ Auto-reader 490 unable to save/read data from memory.	Cycle power to clear error. If error doesn't clear, call for repair or replacement.
E7	Communications Error This error will occur if internal communications have failed.	Call for repair or replacement.
E8	LED Error This error occurs for a specific well if the system detects that a UV LED or Optics Detection circuit is not working.	Cycle power to clear error. If error doesn't clear, call for repair or replacement. Do not use affected incubation well.
E11	BI Inserted Incorrectly Error Incubation time remaining will not display and fluorescent readings are not taken.	Remove BI and inspect to verify cap is closed, glass ampoule is crushed, and growth media is in growth chamber. If necessary, repeat **CLOSE**, **CRUSH, VERIFY,** AND **FLICK** steps to properly activate BI and return BI to well, ensuring it is seated properly.
E12	Power Failure Error Power to Auto-reader was off for too long to provide valid result for affected BI(s).	Ensure power supply connection to Auto-reader is secure.
E14	Ambient Light Error (occupied well) Fluorescent result will not display.	Rely on optional visual pH color change result for BI in affected well. Move 3M™ Attest™ Auto-reader 490 to reduced ambient light conditions to avoid future occurrences.
Other	Unwanted alarm sounds when positive BI detected.	Disable alarm, refer to **3M™ Attest™ Auto-reader 490 Configuration** section for instructions.
Other	Alarm Sounds 3M™ Attest™ Super Rapid Readout Biological Indicator has been removed from incubation/reader well prematurely.	Replace 3M™ Attest™ Super Rapid Readout Biological Indicator in incubation/reader well within 10 seconds to prevent loss of data collected.
Other	LCD Panel does not display properly.	Cycle power. If problem persists call for repair or replacement.
Other	Negative Control Vial BI not properly activated. Media did not contact spore carrier. Control vial was sterilized.	Ensure BI cap is closed and glass ampoule is crushed. Flick BI until media flows to spore chamber at bottom of BI. Use a non-sterilized vial as a control. Check process indicator on BI cap.
Other	Unexplained Positive BI Adhesive residue on vial. Test vial is absorbing fluorescent residue from a chemical indicator or tape.	Do not place tape or labels on vial. Place the vial so it does not come in direct contact with chemical indicators or tape.
Other	3M™ Attest™ Auto-reader 490 will not enter Configuration mode. Pushbutton Configuration may be disabled on 3M™ Attest™ Auto-reader 490 Web App.	On 3M™ Attest™ Auto-reader 490 Web App Configuration Page, go to Pushbutton Configuration and select the **Enable** radio button. Save changes to begin using new setting.
Other	3M™ Attest™ Auto-reader 490 LCD display flashes and asterisks (***) and/or E11 and/or C4 codes appear on display below unoccupied incubation wells.	Move 3M™ Attest™ Auto-reader 490 away from sunlight or sources of incandescent light.

OPTIONAL 3M™ ATTEST™ AUTO-READER 490 WEB APP

Web Browser Requirements

The Web Interface is designed to be viewed in Internet Explorer 6.0 or higher. Lower versions of Internet Explorer or other browsers may result in some web pages being displayed in a less-than-optimum manner. For best results, switching to Internet Explorer 6.0 or higher is recommended. For full functionality, the use of an HTML5 compliant browser with JavaScript enabled is recommended.

Connecting to the 3M™ Attest™ Auto-reader 490 Web App

To use the 3M™ Attest™ Auto-reader 490 Web App, the 3M™ Attest™ 490 Auto-reader must be connected to the facility network using the supplied Ethernet cable. Consult with your facility IT personnel for assistance with network connectivity. Users may connect to the 3M™ Attest™ Auto-reader 490 Web App using a URL based upon either the 3M™ Attest™ Auto-reader 490 serial number or the IP Address. To view the 3M™ Attest™ Auto-reader 490 Web App from a wireless device such as a mobile hand-held device or a computer on a sub-net different from that to which the 3M™ Attest™ Auto-reader 490 is connected, use the IP Address URL.

Note: To access the 3M™ Attest™ Auto-reader 490 Web App within a secure network, the PC or mobile device must have access to the secure network; options include connecting via a network Ethernet cable, signing in to the facility's wireless network, or connecting via a virtual private network (VPN).

A. Serial number URL

1. Connect the supplied Ethernet cable from the 3M™ Attest™ Auto-reader 490 to an Ethernet jack.
2. Depress the ?Δ button once to display the 3M™ Attest™ Auto-reader 490 6-digit serial number on the left side of the top row of text on the LCD display.
3. Enter http://attestxxxxxx where xxxxxx represents the unit's serial number (e.g. http://attest001127) from Step 2 in PC web browser address bar and press Go.
4. 3M™ Attest™ Auto-reader 490 Web App Status page will display on PC. For future ease of use, add this page to your web browser "Favorites".

B. IP Address URL

The 3M™ Attest™ Auto-reader 490 Web App may also be accessed using either a dynamic or static IP address.

1. Dynamic IP Address

A dynamic IP address is assigned when the Ethernet cable is connected from the 3M™ Attest™ Auto-reader 490 to a live Ethernet jack.

Press and release the ?Δ button twice to display the 3M™ Attest™ Auto-reader 490's dynamic IP address. Enter http://IPaddress (e.g. http://xxx.xx.xxx.xx) in the browser of the mobile hand-held device or computer and press Enter. The 3M™ Attest™ Auto-reader 490 Web App Status page will display.

2. Static IP address

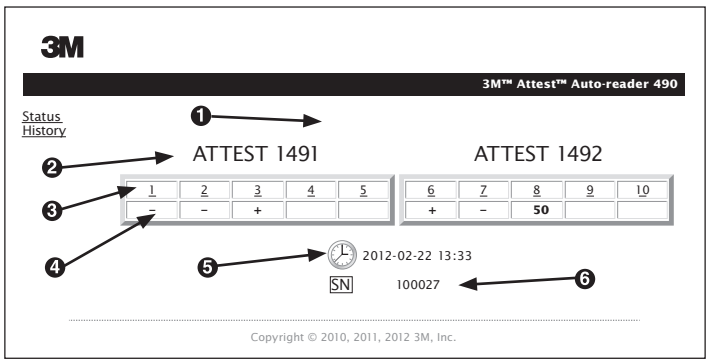
Some facility IT personnel may require devices connecting to the network to use a Static IP address. If this is the case at your facility, contact the IT department to request a Static IP address.

Record the static IP address provided by your facility IT department here: _____. You may wish to label the Ethernet jack with the assigned address. Enter http://StaticIPaddress (e.g. http://xxx.xx.xxx.xx) in the browser address bar on your PC or mobile hand-held device and press Enter. The 3M™ Attest™ Auto-reader 490 Web App Status page will display.

About the 3M™ Attest™ Auto-reader 490 Web App Pages

The 3M™ Attest™ Auto-reader 490 Web App includes four pages:

a) Status page



1. User-entered nickname (optional)
2. Well Configuration (1-5 and 6-10)
3. Well Number
4. BI Result/Remaining Incubation Time
5. Date and Time
6. 3M™ Attest™ Auto-reader 490 Serial Number

The Status page provides a real-time representation of the 3M™ Attest™ Auto-reader 490 configuration and LCD panel display. The current date and time and 3M™ Attest™ Auto-reader 490 serial number are also indicated on this page. From this page, the user may navigate to:

- the History page by clicking on History on the left of the screen.
- the Results Detail page by clicking on the well number of an occupied well (i.e. a well that currently has an incubating BI). Clicking on an unoccupied well takes the user to the History page.

b) Results Detail page

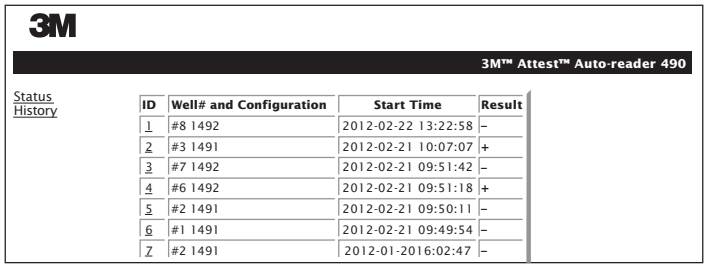
This page provides an individual record for an incubated BI. For complete documentation, the user may print a hard copy and/or save the record as an electronic file.

Note 1: The top four rows (highlighted in green) are populated automatically by the 3M™ Attest™ Auto-reader 490 and cannot be changed by the user. The remaining rows are completed by the user to satisfy the documentation requirements of their facility.

Note 2: The Results Detail page refreshes less frequently that the Status page. Until the BI result is available, the Results Detail page displays remaining minutes of incubation in the results field.

GB

c) History page

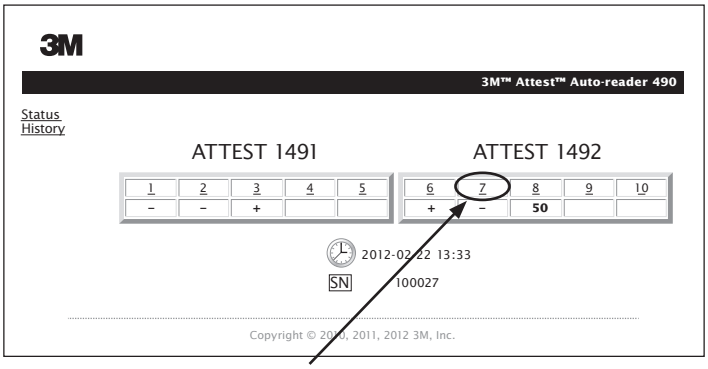


The 3M™ Attest™ Auto-reader 490 stores results for the last 100 incubated BIs on embedded software. The 3M™ Attest™ Auto-reader 490 Web App History page provides a summary of these last 100 results.

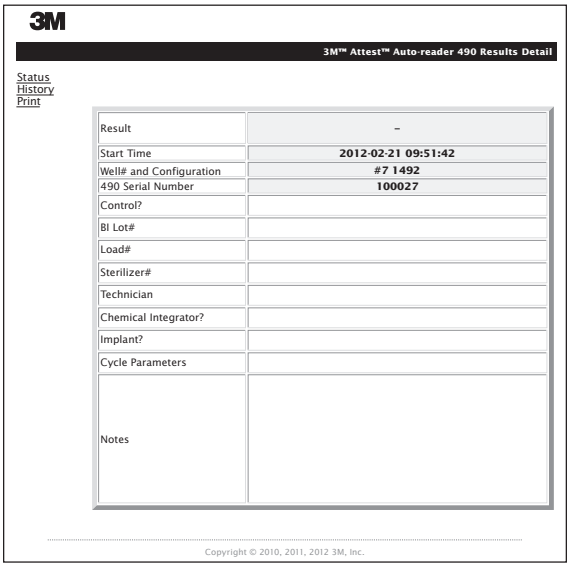
d) Configuration page

This page allows the configuration of the 3M™ Attest™ Auto-reader 490's network settings and Language from the 3M™ Attest™ Auto-reader 490 Web App.

Documenting BI Results using the 3M™ Attest™ Auto-reader 490 Web App



1. **Open the Results Detail page**
   After inserting a new 3M™ Attest™ Super Rapid Readout BI in the 3M™ Attest™ Auto-reader 490, it is a best practice to open the 3M™ Attest™ Auto-reader 490 Web App Results Detail page for that BI by clicking on the appropriate well number from the Status page.
2. **Enter** the specific information for that BI (e.g. BI Lot #, sterilizer/load number, Technician name, etc.) in the provided editable fields. Use the Notes section to capture information not prescribed in the provided row titles, for example, you may wish to use this field to record load items.

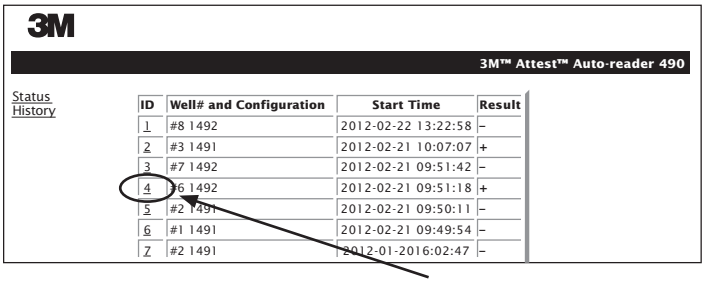


3. The entered information is **saved** automatically to temporary web browser storage on the user's PC every 60 seconds, or by leaving the Results Details page.
4. **Print/File**. Once the BI result is available, print or file the Results Detail page to create a record. The page may be physically printed and/or saved as an electronic file.

Important! Data is only stored for the last 100 incubated BIs.

Embedded software in the 3M™ Attest™ Auto-reader 490 saves the data from the auto-populated (i.e. green highlighted) fields. The application relies on the temporary storage in the user's web browser to save the data in the user-populated fields. In both cases, data is only stored for the last 100 records i.e., the 101st incubated BI will erase the information saved for the 1st incubated BI. To retain the Results Detail information for future reference it is best practice to print the page as soon as the BI result is available.

Using the BI History Page



To view or print an individual record, click on the ID number of the desired record to navigate to the Results Detail page for that BI.

Note 1: Column 1, "ID" is the assigned ID number with ID 1 representing the newest record and ID 100 representing the oldest record. To help find a particular record, all columns are sortable, simply click once on the column heading to sort in ascending order and click a second time to reverse the order.

Note 2: The History page refreshes less frequently than the Status page. Until the BI result is available, the History page displays ••• in the Results column indicating incubation is still in-process.

Using the Configuration Page

Certain set-up and configuration options are available on the password protected 3M™ Attest™ Auto-reader 490 Web App Configuration page. Ideally, the 3M™ Attest™ Auto-reader 490 should be empty (i.e. have no incubating BIs) when it is reconfigured. Navigate to the Configuration page by entering either:

1) http://attestxxxxxx/protect/config.htm (where xxxxxx is the 6-digit unit serial number), or

2) http://xxx.xx.xxx.xx/protect/config.htm (where xxx.xx.xxx.xx is the IP address) in the web browser address bar and pressing Go or enter. A security screen will appear. Fill in the editable fields as follows:

User name: manager

Password: Attest

and press OK.

Click on the desired radio buttons to change settings.

Auto-reader Type	Select the configuration desired for wells 1-5/6-10 by clicking on the appropriate radio button.
Language	Selected setting indicates language in which text on 3M™ Attest™ Auto-reader 490 Web App pages will appear on the computer/smart phone screen.
Pushbutton Configuration	Selecting **Enable** ⦿ allows the user to configure the 3M™ Attest™ Auto-reader 490 from the buttons on the unit itself. Selecting **Disable** ⦿ prevents the user from being able to configure the 3M™ Attest™ Auto-reader 490 from the buttons on the unit itself.
Buzzer Configuration	Selecting **Enable** ⦿ enables the audible alarm. The speaker icon will appear on the LCD panel. Selecting **Disable** ⦿ disables the audible alarm. The speaker icon will disappear from the 3M™ Attest™ Auto-reader 490 LCD panel.
Attest Auto-reader 490 Nickname	Naming the 3M™ Attest™ Auto-reader 490 may be useful in facilities with multiple units. The assigned nickname will appear on the 3M™ Attest™ Auto-reader 490 Web App Status page.
Enable DHCP	Default: setting is checked indicating the Web App will use the Dynamic IP address automatically assigned when the 3M™ Attest™ Auto-reader 490 is connected to the network. Remove the check if you wish to use a Static IP address assigned by your facility IT.
IP Address	Enter Static IP address assigned by IT
Gateway	Enter Gateway
Subnet Mask	Enter Subnet Mask
Primary DNS	Enter Primary DNS
Use Computer Time	Check this box if you wish to set the clock on-board the 3M™ Attest™ Auto-reader 490 using the computer's clock.
Attest Auto-reader 490 Time	Alternatively, leave the Use Computer Time box unchecked and complete the date and time boxes to set the 3M™ Attest™ Auto-reader 490 clock.

After changing desired settings, click on Save Config button to save your changes. A new screen confirming the settings were successfully changed appears.

TROUBLESHOOTING THE 3M™ ATTEST™ AUTO-READER 490 WEB APP

Issue	Problem	Solution
Unable to access 3M™ Attest™ Auto-reader 490 Web App on networked computer	3M™ Attest™ Auto-reader 490 and/or computer not connected to network.	Ensure 3M™ Attest™ Auto-reader 490 Ethernet cable is connected to a live jack and that connection to 3M™ Attest™ Auto-reader 490 is secure. Ensure computer is connected to network. If failure is with connection attempted using 3M™ Attest™ Auto-reader 490 serial number URL, try connecting using IP address URL. Contact facility IT or 3M if problem persists.
Unable to access 3M™ Attest™ Auto-reader 490 Web App on mobile device	3M™ Attest™ Auto-reader 490 not connected to network. For security reasons, facility firewall may prevent mobile devices not connected to the facility network from connecting to secure IP addresses.	Ensure 3M™ Attest™ Auto-reader 490 Ethernet cable is connected to a live jack and that connection to 3M™ Attest™ Auto-reader 490 is secure. Contact facility IT for their recommendation on connecting to the secure network. Solutions may include enabling WiFi on the mobile device and signing into the facility network or connecting to the facility virtual private network (VPN) on the mobile device.
Data entered by user on Results Detail page disappears	User entered data is written to temporary web browser storage. Browser may have cleared data.	Set web browser to accept (allow or enable) cookies. As a best practice, print or save Results Detail record as soon as BI result is final.
BI result displayed on 3M™ Attest™ Auto-reader 490 LCD panel does not appear on Results Detail page	The Results Detail page has not refreshed yet.	Use your browser to refresh the Results Detail page, or wait up to 60 seconds for the page to automatically refresh.
Results Detail page will not open from the Status page	The Results Detail page only opens from the Status page for occupied 3M™ Attest™ Auto-reader 490 wells.	Do not attempt to navigate to the Results Detail page from unoccupied wells on the Status page.

REPAIR AND REPLACEMENT

In the U.S.A., 3M™ Attest™ Auto-reader 490s must be repaired at:

3M Health Care Service Center
Suite 200, Bldg. 502
3350 Granada Avenue North
Oakdale, MN 55128
1-800-292-6298
Fax: 1-800-770-8016

Outside of the U.S.A., contact your local 3M Subsidiary.

If you have questions, call our Customer Service number: 1-800-292-6298.

CE

Made in the U.S.A. by

3M Health Care

2510 Conway Ave
St. Paul, MN 55144
1-800-228-3957
www.3M.com/healthcare

© 2013, 3M. All rights reserved.
3M and Attest are trademarks of 3M.
Used under license in Canada.

3M

Made in the U.S.A. by

3M Health Care

2510 Conway Ave.
St. Paul, MN 55144
1-800-228-3957

www.3M.com/healthcare

CE

EC REP **3M Deutschland GmbH**
Health Care Business
Carl-Schurz-Str. 1
41453 Neuss
Germany

© 2013, 3M. All rights reserved.
3M and Attest are trademarks of 3M.
Used under license in Canada.

Issue Date: 2013-07
34-8713-0856-4